REMARKS

In an Office Action dated March 8, 2005, claims 13, and 15-36, all pending claims, were rejected. By amendment above, claims 13, 27, and 36 have been rewritten and claims 19-21 have been cancelled. Support for the amendments to claims 13, 27, and 36 can be found in these claims as originally filed.

Reconsideration of this application and allowance of the claims is respectfully requested in view of the foregoing amendments and the following remarks.

Claims 13, 15-21, and 23-36 were rejected under 35 U.S.C. §102(e) as being anticipated by Andya et al (US 6,267,958) for reasons of record. In short the Examiner asserted that Andya et al teach a variety of lyophilizates comprising monoclonal or polyclonal antibodies, sugars, amino acids, and surfactants wherein the lyophilizate is essentially free of polyethylene glycols and additional proteins. According to the Examiner Andya et al also teach a variety of lyophilizates as described above further including an inorganic acid as a buffering agent. The Examiner has considered applicants' response to the previous Office Action and found the arguments therein not persuasive. Applicants submitted that the composition and method claimed is directed to preparing a lyophilizate containing no polyethylene glycols or additional proteins. Applicants further argued that one skilled in the art would not have even considered that the compositions and methods claimed are disclosed by or inherent to the composition of Andya et al. According to the Examiner applicants have not provided such evidence. Moreover, the Examiner asserts that applicants have not provided

evidence establishing a patentable difference between the method or product claims of a lyophilizate containing no polyethylene glycols or additional proteins, with the method or product used in the cited prior art. According to the Examiner, Andya et al does not appear to specifically require polyethylene glycol or additional proteins. Therefore, the Examiner asserts that any argument alleging that the present claims differ from the prior art because of the limitation "no polyethylene glycol or additional proteins" is not pertinent because this says nothing about the patentable difference between the method or product used in the prior art and the current pending claims.

Applicants submit that independent claims 13, 27 and 36, as amended, are directed to include an amino sugar as a protectant/stabilizing component in the composition, as opposed to requiring the composition to include either a sugar or an amino sugar. Amending claim 13 to include an amino sugar as described above, leaves claims 19-21 without antecedent basis, which claims therefore have been cancelled. Andya et al discloses a lyphilizate comprising an antibody, a sugar, at least one amino acid and a surfactant as asserted by the Examiner. However, Andya et al does not disclose the use of an amino sugar in stabilizing a lyophilizate of an antibody as claimed in claims 13, 27, and 36, as amended. For this reason claims 13, 27, and 36, as amended, are not anticipated by Andya et al. Therefore, applicants submit that claims 13, 15-21, and 23-36 of the present application are not anticipated by Andya et al. Withdrawal of the rejection is respectfully requested.

Further, claims 13, 15-36 were rejected under 35 U.S.C.§103(a) as obvious over Andya et al (US 6,267,958) in view of Michaelis et al (US 5,919,443) for reasons of record. In short, Andya et al is applied as above, whereas the Examiner asserts that Andya et al does not include the teaching of an amino sugar such as glucosamine, N-methyl-glucosamine, galactosamine, and neuraminic acid. According to the Examiner, Michaelis et al teach the advantages of an improved lyophilizate which contains amino sugars. Therefore, according to the Examiner it would be obvious to combine the teachings of Andya et al with Michaelis et al. In addition, the Examiner has considered applicants' response to the previous Office Action and found the arguments not persuasive. Applicants submitted that not all elements of the claimed invention are disclosed by Andya et al or Michaelis et al either alone or in combination, because the claims specifically exclude the use of polyethylene glycol and additional proteins. According to the Examiner the suggestion to combine the prior art references was because Michaelis et al disclose that it is possible to produce stable forms of pharmaceutical agents when amino sugars are used as additives. The Examiner asserts that the combined teachings are discussed in view of the fact that both references represent analogous teachings comprising the preparation of stable pharmaceutical compositions.

Applicants submit that the claims, as amended, are directed to stabilizing an antibody lyophilizate with an amino sugar, at least one amino acid, and a surfactant. Andya et al does not teach or suggest the use of an amino sugar to stabilize a

lyophilizate of an antibody. This failure in Andya et al is not cured by Michaelis et al, which is directed to stabilization of lyophilized pharmaceutical preparations of G-CSF. Although Michaelis et al disclose the use of an amino sugar as a stabilizing agent, the reference is directed to stabilizing G-CSF. The non-glycosylated single polypeptide chain G-CSF is very different from the complex antibodies of the currently claimed invention. Therefore, there is no motivation to combine the cited references to teach or suggest the use of an amino sugar in stabilizing an antibody lyophilizate as in the amended claims. Therefore, applicants submit that claims 13, and 15-36 of the present application are not obvious over Andya et al. in view of Michaelis et al. Withdrawal of the rejection is respectfully requested.

Applicants submit that the present application is now in condition for allowance. Reconsideration and favorable action are earnestly requested.

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